IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALNYLAM PHARMACEUTICALS, INC., Plaintiff, v. MODERNA, INC., MODERNATX, INC., and MODERNA US, INC., Defendants	C.A. No. 22-cv-335-CFC **JURY TRIAL DEMANDED**

DEFENDANTS' OPENING BRIEF IN SUPPORT OF THEIR PARTIAL MOTION TO DISMISS PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 12(B)(6)

Dated: May 23, 2022

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TABLE OF CONTENTS

TABLE OF AUTHORITIES[1]

Page(s)

Cases

[1] Unless otherwise indicated, internal quotation marks and citations have been omitted from quoted material.

Statutes

Rules

Other Authorities

I. INTRODUCTION

The COVID-19 pandemic has presented an urgent and historic public health challenge. Moderna acted swiftly and worked tirelessly to meet that challenge, providing the U.S. Government with a vaccine to a novel, deadly, and highly contagious pathogen in record time.

Congress envisioned exactly such cooperation when it enacted 28 U.S.C. § 1498(a) to encourage suppliers "to furnish what [is] needed by the government, without fear of becoming liable themselves for infringements to . . . the owners or assignees of patents." This important statutory protection covers all suppliers the U.S. Government appropriately authorizes, and played a critical role in encouraging companies to step up to help fight the COVID-19 pandemic.

When the pandemic started, Moderna was a comparatively small biotech company in Cambridge, Massachusetts, pioneering a new class of medicines made of messenger RNA ("mRNA"). These medicines have the potential to treat and prevent many diseases—from infectious diseases like influenza and HIV, to autoimmune and cardiovascular diseases, as well as rare forms of cancer. Over the past twelve years, Moderna has pioneered several fundamental breakthroughs in the field of mRNA technology. These discoveries span all aspects of mRNA medicines—from the characteristics and design of the mRNA itself and the protein it encodes, to the technologies to deliver mRNA to patients safely and effectively.

Moderna was thus positioned to quickly pivot when the crisis struck, develop the COVID-19 Vaccine in record time, and save countless lives.

Alnylam now seeks royalties for Moderna's COVID-19 Vaccine, also called "Spikevax®." But Moderna supplied the vaccine to the U.S. Government as part "of the national emergency response to . . . COVID-19[], for the United States Government . . . and the US population." In its contract with Moderna, the Government expressly invoked sovereign authority to "authorize[] and consent[] to all use and manufacture . . . of any invention described in and covered by a United States patent." Accordingly, Alnylam's claims here can only proceed against the Government in the Court of Federal Claims under Section 1498.

Moderna will demonstrate that its COVID-19 Vaccine does not infringe any valid patents, including those held by Alnylam. But that dispute is for later. The only issue now is where and against what party Alnylam may seek damages for U.S. Government sales. Under Section 1498, when an allegedly infringing product is "used or manufactured by or for the United States," the only remedy for the alleged infringement is an "action against the United States in the United States Court of Federal Claims." Thus, because Alnylam seeks royalties on the sale and provision of COVID-19 Vaccine doses to the U.S. Government, its claims on those sales can only proceed against the Government in the Court of Federal Claims.

II. NATURE AND STAGE OF THE PROCEEDINGS

On Mach 17, 2022, Plaintiff Alnylam Pharmaceuticals, Inc. ("Alnylam") filed this action for patent infringement against Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. (together, "Moderna"). Alnylam alleges that Moderna's mRNA-1273 COVID-19 Vaccine infringes Plaintiff's patent No. 11,246,933. *E.g.* D.I. 1 ("Compl."), ¶¶ 2, 44–48.

III. SUMMARY OF ARGUMENT

The Court should dismiss Alnylam's infringement claims (both direct and indirect) based on supplies to the U.S. Government. Under 28 U.S.C. § 1498(a), Alnylam's only remedy is an action against the U.S. Government in the Court of Federal Claims.[2]

IV. STATEMENT OF FACTS

The facts here come from the Complaint and matters of public record, including Moderna's COVID-19 Vaccine contract with the U.S. Government. The contract is widely available, including on the website for the Department of Health

[2] Moderna's motion addresses part of the complaint and thus suspends the time to respond to the remaining allegations in the complaint. *See* Fed. R. Civ. P. 12(a)(4)(A); *see also Circuit City Stores, Inc. v. Citgo Petroleum Corp.*, No. CIV. A. 92-CV-7394, 1994 WL 483463, at *4 (E.D. Pa. Sept. 7, 1994) ("A partial 12(b) motion enlarges the time to file an answer."); *Godlewski v. Affiliated Comput. Servs., Inc.*, 210 F.R.D. 571, 572 (E.D. Va. 2002) ("A majority of courts . . . hold that the filing of a motion that only addresses part of a complaint suspends the time to respond to the entire complaint, not just to the claims that are the subject of the motion.").

and Human Services.[3] Moderna attaches the contract as Exhibit A to this brief for the Court's convenience.

A. Moderna's Government Contract

Moderna's contract sets out the background of the pandemic and the Government's response. "In December 2019, a novel coronavirus now known as SARS-CoV-2 was first detected . . . , causing outbreaks of the coronavirus disease COVID-19 that has now spread globally." Ex. A at 19 C. 1.1. As a result, the "Secretary of Health and Human Services declared a public health emergency on January 31, 2020," and "[o]n March 1, 2020, the President of the United States . . . proclaimed that the COVID-19 outbreak in the United States constitute[d] a national emergency." *Id.* Under Operation Warp Speed, "the Department of Defense and HHS [led] a whole of nation effort to ensure development of promising vaccine, diagnostic and therapeutic candidates and ensure that these medical countermeasures" would be "available in the quantities required to reduce SARS-CoV-2 transmission, identify prior and/or current infection, and improve patient care, thereby mitigating the impact of COVID-19 on the nation and its people." *Id.* at C.1.1.1.

[3] *See, e.g.*, https://www.hhs.gov/sites/default/files/moderna-covid-19-vaccine-contract.pdf.

Contracting expertise was critical to the effort. "The DoD Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense" provided "expertise and contracting support to HHS[.]" *Id.* As candidate products progressed "to clinical trials to evaluate the safety and efficacy of vaccines and therapeutics," it was "critical that, in parallel," the Government would support "large scale manufacturing so that vaccine doses or therapeutic treatment courses are immediately available for nationwide access as soon as a positive efficacy signal is obtained and the medical countermeasures are authorized for widespread use." *Id.*

Consistent with that mission, the U.S. Army Contracting Command contracted with Moderna in August 2020 (Ex. A at 1-2), even before the FDA had granted Emergency Use Approval to Moderna's COVID-19 Vaccine in December 2020 (Compl. ¶¶ 16, 51). The contract includes a list of "Federal Acquisition Regulations" that were "incorporated by reference." Ex. A at 45–47, 51. Among these is the express "authorization and consent" provision of FAR 52.227-1 (*id.* at 46), by which "[t]he Government authorizes and consents to all use and manufacture, in performing this contract or any subcontract at any tier, of any invention described in and covered by a United States patent. . . " (Federal Acquisition Regulation ("FAR") 48 C.F.R. § 52.227–1(a) (2020)). This authorization and consent is broad, covering among other things patents on "the structure or composition of any article

the delivery of which is accepted by the Government under this contract." FAR 52.227-1(a)(1).

Moderna succeeded in delivering what the Government needed. Moderna's "vaccine against COVID-19, mRNA-1273, was designed, subject to Phase 1, Phase 2 and Phase 3 clinical trials, delivered clinical trial results, and received [regulatory] authorizations in less than a year, and has been and continues to be a key tool in fighting the global COVID-19 pandemic." D.I. 1-1 at 307 (Compl. Ex. 3). It "has been administered to hundreds of millions of people around the world, protecting people from COVID-19 infection, hospitalization and death." *Id.* at 665 (Compl. Ex. 14).

This remarkable success was made possible by the years of intensive technical development that Moderna had put into mRNA technology before the pandemic began. *E.g.*, *id.* at 643 (Compl. Ex. 9) ("Our speed in developing the Moderna COVID-19 vaccine was ultimately a product of our many years of research and investment in mRNA vaccines."); *id.* at 651 (Compl. Ex. 11) ("Over the past nine years, Moderna has invested in creating and developing a novel platform for designing and manufacturing a new class of mRNA-based vaccines. The investments in this proprietary platform have enabled Moderna to expeditiously create, manufacture and clinically develop mRNA-1273 to potentially address the current COVID-19 pandemic."); *id.* at 682 (Compl. Ex. 16) ("We have been able to

research and develop mRNA-1273 so quickly because we leveraged our prior research on vaccines and other mRNA-based medicines."). One key factor was Moderna's investment and innovation in the design of lipid nanoparticles ("LNPs") and their component lipids. *See, e.g.*, *id.* at 682 (Compl. Ex. 16) ("[A] key challenge in developing mRNA vaccines and treatments has been to develop a vehicle for getting the mRNA into the cell … After years of effort, Moderna has developed a proprietary lipid-nanoparticle-delivery system that enhances safety and tolerability."). Moderna "invested heavily in … LNP technologies to enable delivery of larger quantities of mRNA" and developed "extensive in-house expertise in medicinal chemistry" which generated "fundamental discoveries about … structural motifs of lipids and LNP performance[.]" *Id.* at 301 (Compl. Ex. 3).

B. The Complaint

Notwithstanding Moderna's innovation, Alnylam alleges that Moderna's COVID-19 vaccine includes a lipid, SM-102, that infringes an Alnylam patent. Compl. ¶¶ 1–2, 44–49.

Alnylam's Complaint completely ignores the existence of Moderna's contract with the Government. Nor does the Complaint contain any indication that Alnylam ever approached the Government to seek compensation. Alnylam instead brought this action, which includes and does not carve-out purchases by the U.S.

Government. Compl. ¶¶ 39 (referring to Moderna's "sales of 807 million doses"), 47 ("every dose"), 50–53.

V. ARGUMENT

A. Legal Standards

Under Rule 12(b)(6), a complaint should be dismissed, in whole or in part, if the allegations fail to give rise to a "plausible" claim for relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). As an affirmative defense, Section 1498 immunity provides a basis for dismissal under Rule 12(b)(6) when the elements of the defense appear on the face of the complaint. *D3D Techs., Inc. v. Microsoft Corp.*, No. 6:20-CV-1699-PGB-DCI, 2021 WL 2194601, at *2 (M.D. Fla. Mar. 22, 2021); *ALA, Inc. v. CCAIR, Inc.*, 29 F.3d 855, 859 (3d Cir. 1994). In considering a 12(b)(6) motion, the Court must take the complaint's plausible allegations as true, and may also consider any "document integral to or explicitly relied upon in the complaint," matters of public record, and items subject to judicial notice. *Angstadt v. Midd-West Sch. Dist.*, 377 F.3d 338, 342 (3d Cir. 2004); *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 322 (2007) (court may consider "matters of which [it] may take judicial notice"); *Twombly*, 550 U.S. at 568 n.13 (court may consider "the full content of the published articles referenced in the complaint . . ."); *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (holding that "document[s]

integral to or explicitly relied upon in the complaint" may be considered in connection with a motion to dismiss); Fed. R. Evid. 201; *Williams v. Magee*, No. 1:19-CV-720, 2019 WL 3337085, at *4 (M.D. Pa. July 24, 2019) (court may consider "matters of public record").

Here, Moderna's government contract is a matter of public record subject to judicial notice. The contract is published on the website of the Department of Health and Human Services, one of the agreement's parties. *See* Ex. A, https://www.hhs.gov/sites/default/files/moderna-covid-19-vaccine-contract.pdf. Courts may, and routinely do, take judicial notice of government websites and contracts, the existence and contents of which are not subject to reasonable dispute. *Williams*, 2019 WL 3337085, at *4 ("The Court may take judicial notice of publicly available documents, including publicly-executed contracts involving governmental entities . . . ."); *Inman v. Technicolor USA, Inc.*, No. CIV.A. 11-666, 2011 WL 5829024, at *4 (W.D. Pa. Nov. 18, 2011) (taking judicial notice of publicly available user agreement when there was no dispute as to authenticity); *London v. Del. Dep't of Corr.*, No. CV 19-1518-MN-SRF, 2021 WL 3422360, at *7 n.15 (D. Del. Aug. 5, 2021), *report and recommendation adopted*, No. CV 19-1518 (MN), 2021 WL

4262458 (D. Del. Sept. 20, 2021) (taking judicial notice of government website as a matter of public record).[4]

Alnylam's avoidance of the terms of the contract in their Complaint cannot deprive this Court of the ability to consider it. *See In re Burlington*, 114 F.3d at 1426 ("Plaintiffs cannot prevent a court from looking at the texts of the documents on which its claim is based by failing to attach or explicitly cite them."). Nor would it make sense to proceed as if the contract does not exist. The whole point of the authorization and consent term in the contract is to ensure that the case proceeds in the correct forum (the Court of Federal Claims) against the correct party (the Government). The Court accordingly should consider the contract here and dismiss the claims that are based on it.

[4] In addition to being cited on HHS.gov, the contract is also publicly available on other government websites, like SEC.gov, and as part of Moderna, Inc.'s Form 10-Q with the Securities and Exchange Commission ("SEC"). Moderna (Form 10-Q) Quarterly Report (Oct. 30, 2020) at 30 (https://www.sec.gov/ix?doc=/Archives/edgar/data/0001682852/000168285220000023/mrna-20200930.htm); Exhibit 10.3 (Contract No. W911QY20C0100) https://www.sec.gov/Archives/edgar/data/1682852/000168285220000023/exhibit103.htm. Courts may also take judicial notice of public filings, like those with the SEC. *Novartis Pharms. Corp. v. Handa Neuroscience, LLC*, No. CV 21-645-LPS, 2022 WL 610771, at *4 n.1 (D. Del. Mar. 1, 2022); *cf. Southmark Prime Plus, L.P. v. Falzone*, 776 F. Supp. 888, 892 (D. Del. 1991) (taking judicial notice of SEC filings when considering motion for judgment on the pleadings, applying the same standards as for a motion to dismiss under 12(b)(6)).

B. The Court Should Dismiss Claims Based on U.S. Sales under 28 U.S.C. § 1498(a)

Every patent granted by the U.S. Government comes with a caveat—the patentee's monopoly may not inhibit the Government from having suppliers work on its behalf to make or use an invention, subject to compensation in the Court of Federal Claims. To that end, the "government has graciously consented" in Section 1498 "to be sued in the Claims Court for reasonable and entire compensation, for what would be infringement if by a private person." *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 842 F.2d 1275, 1283 (Fed. Cir. 1988).

Section 1498(a) provides that, whenever "an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license . . . or lawful right to use or manufacture the same," "the owner's remedy shall be by action against the United States in the United States Court of Federal Claims[.]" The statute thus seeks "to stimulate contractors to furnish what [is] needed by the government, without fear of becoming liable themselves for infringements to inventors or the owners or assignees of patents" (*Astornet Techs. Inc. v. BAE Systems, Inc.*, 802 F.3d 1271, 1277) and to "enabl[e] the Government to purchase goods for the performance of its functions without the threat of having the supplier enjoined from selling patented goods to the Government" (*Coakwell v. United States*, 372 F.2d 508, 511 (Ct. Cl. 1967)). The statute was amended over a century ago specifically "to prevent patent infringement

suits from interfering with the supply of war materials during World War I," as "Congressional concern was that if contractors feared an infringement suit, they might decide not to manufacture desperately-needed products for the United States' war effort." *Saint Switch v. Gen. Motors of Can.*, No. 95 C 0250, 1996 U.S. Dist. LEXIS 2762, at *5–6 (N.D. Ill. Mar. 7, 1996) (internal citations omitted).

Few situations are more within the heart of Section 1498 than the COVID-19 crisis. The Government declared emergencies twice in the pandemic's wake—a "public health emergency" in January 2020 and a "national emergency" in March 2020. Ex. A at 19 C.1.1. The Government then enlisted the Department of Defense to help the Department of Health and Human Services rally the private sector to develop and distribute a vaccine as quickly as possible. *Id.* at 19 C.1.1.1. Moderna answered the call. Then a relatively small biotech company, Moderna had the right expertise at the right time. Moderna scientists and their collaborators worked to develop and produce a COVID-19 vaccine for distribution on a massive scale while much of the rest of the country quarantined, as government and private industry worked together to respond to the most severe crisis facing the nation. This is exactly when Section 1498 is meant to apply.

By its terms, Section 1498(a) has only two requirements. The allegedly infringing use must be "for the Government," and it must have "the authorization and consent of the Government." *Sevenson Env't Servs., Inc. v. Shaw Env't, Inc.*,

477 F.3d 1361, 1365 (Fed. Cir. 2007) (citing *Hughes Aircraft Co. v. United States*, 534 F.2d 889, 897–98 (Ct. Cl. 1976)). Moderna's sale and provision of COVID-19 Vaccine doses to the U.S. Government satisfy these criteria.

1. Moderna Sold and Provided COVID-19 Vaccine Doses to the U.S. Government "for the Government"

Moderna's supply of its COVID-19 Vaccine is deemed "for the Government" under Section 1498(a) so long as the supply is "for the benefit of the [G]overnment." *Advanced Software Design Corp. v. Fed. Rsrv. Bank of St. Louis*, 583 F.3d 1371, 1378 (Fed. Cir. 2009). In other words, "[a] use is 'for the Government' if it is 'in furtherance and fulfillment of a stated Government policy' which serves the Government's interests and which is 'for the Government's benefit.'" *IRIS Corp. v. Japan Airlines Corp.*, 769 F.3d 1359, 1362 (Fed. Cir. 2014) (quoting *Madey v. Duke Univ.*, 413 F. Supp. 2d 601, 607 (M.D.N.C. 2006)).

Moderna's contract is explicit that it is for the benefit of the Government, describing the agreement as "for the United States Government . . . and the US population." Ex. A at 19 C.1. The contract then goes further and contains provisions explaining how the agreement fits into government policy. The contract's "Scope" section recounts the COVID crisis, the Government's emergency declarations in response, and the commencement of Operation Warp Speed. *Id*. at 19 C.1.1, C.1.1.1. Under the operation, "the Department of Defense and HHS" led "a whole of nation effort to ensure development of promising vaccine, diagnostic and therapeutic

candidates and ensure that these medical countermeasures are available in the quantities required to reduce SARS-CoV-2 transmission … and improve patient care, thereby mitigating the impact of COVID-19 on the nation and its people." *Id.* at C.1.1.1. The Department of Defense "Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense" provided "expertise and contracting support to HHS[.]" *Id.* The Government's whole purpose was to support "large scale manufacturing so that vaccine doses . . . are immediately available for nationwide access as soon as a positive efficacy signal is obtained and the medical countermeasures are authorized for widespread use." *Id.*

In short, Moderna supplied, and continues to supply, COVID-19 Vaccine doses to the U.S. Government for the Government to achieve a specific government objective (*i.e.*, supporting a nationwide vaccination effort). *Cf. Thermalon Indus., Ltd. v. United States*, 34 Fed. Cl. 411, 420 (Fed. Cl. 1995) ("Hence, for example, if the United States purchases vaccines for administration to the public in order to eradicate a particular disease, the government not only would be engaged in the purchase and sale of specific goods, but also would be concurrently exercising its sovereign power for the general public welfare.").

2. Moderna Had "the Authorization and Consent of the Government"

Moderna supplied, and continues to supply, COVID-19 vaccine under express authorization and consent from the Government, regardless of any issued patents.

Under Section 1498(a), the Government's "authorization or consent" can be express or implied. *TVI Energy Corp. v. Blane*, 806 F.2d 1057, 1060 (Fed. Cir. 1986). An authorization and consent provision in a government contract establishes "authorization and consent" under Section 1498(a). *Crater Corp. v. Lucent Tech., Inc.*, 255 F.3d 1361, 1368 (Fed. Cir. 1976); *see also D3D Techs.*, 2021 WL 2194601, at *2 (satisfying authorization and consent prong when contract "show[ed] the Government expressly authorized the alleged infringing activity").

Here, the Government explicitly authorized and consented to Moderna's manufacture and sale of the COVID-19 Vaccine. The contract incorporates by reference FAR 52.227-1, entitled "Authorization and Consent." Ex. A at 46. That regulation provides that:

> **The Government authorizes and consents to all use and manufacture, in performing this contract or any subcontract at any tier, of any invention described in and covered by a United States patent- (1) Embodied in the structure or composition of any article the delivery of which is accepted by the Government under this contract**; or (2) Used in machinery, tools, or methods whose use necessarily results from compliance by the Contractor or a subcontractor with (i) specifications or written provisions forming a part of this contract or (ii) specific written instructions given by the Contracting Officer directing the manner of performance.

FAR 52.227-1(a) (2020) (emphasis added).[5]

Alnylam alleges that Moderna's COVID-19 Vaccine includes a lipid covered by its patent. Compl. ¶¶ 2, 13–15, 34–37. It further alleges that this lipid facilitates delivery of the operative mRNA. *Id.* ¶¶ 24, 40–43. As alleged, the lipid is accordingly part of and embodied in the "structure or composition" of the article covered by the contract—namely, the COVID-19 Vaccine. In these circumstances—when a patented article of manufacture is incorporated into a supply contract—the first clause of FAR 52.227-1 controls. *See Carrier Corp. v. United States*, 534 F.2d 244, 247 n.5 (Ct. Cl. 1976) ("The portion of the authorization and consent clause that provides that the Government authorizes and consents to infringement of any patent 'embodied in the structure or composition of any article the delivery of which is accepted by the Government' is applicable to hardware and other goods procured by and delivered to the Government for its own use, generally through supply contracts.").

Accordingly, the agreement meets both prongs of Section 1498(a). Insofar as Alnylam continues to pursue allegations based on U.S. sales, it must do so in the Court of Federal Claims.

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[5] The contract also incorporates by reference FAR 52.227-1 Alternate I (Ex. A at 46), which provides an alternate and broader provision, used in contracts for research and development (*see* FAR 27.201-2(a)(2) (2020)).

3. Indirect Infringement Allegations Are Also Subject to Section 1498(a)

Alnylam also alleges that Moderna indirectly infringes by supplying COVID-19 vaccine doses to the Government. *See* Compl. ¶ 52. This allegation likewise does not circumvent Section 1498(a).

Section 1498(a) bars indirect infringement claims when the underlying act of direct infringement is performed by or for the Government. *Astornet*, 802 F.3d at 1277–78 (indirect infringement claim against government contractor barred where the alleged infringement was performed by the Transportation Security Administration using the contractor's equipment). Put differently, simply appending claims of indirect infringement here is "insufficient to undercut the clear directive in § 1498(a) as to the exclusive nature of the remedy provided therein." *Morpho Detection, Inc. v. Smiths Detection Inc.*, No. 2:11CV498, 2013 WL 5701522, at *4–5 (E.D. Va. Oct. 17, 2013).

VI. CONCLUSION

Moderna respectfully requests that the Court grant its motion pursuant to Rule 12(b)(6) and dismiss with prejudice Plaintiff's claims based on Moderna's sale and provision of COVID-19 Vaccine doses to the U.S. Government. *D3D Techs.*, 2021 WL 2194601, at *2 (granting Rule 12(b)(6) motion, dismissing claims involving sales to the U.S. Government under § 1498); *IRIS Corp.*, 769 F.3d at 1283 (affirming Rule 12(b)(6) dismissal under § 1498).

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the length, type, and font limitations set forth in Judge Connolly's Standing Order Regarding Briefing in All Cases (Nov. 6, 2019) because it is prepared in 14-point Times New Roman typeface, and contains 3,890 words out of a permitted 5,000, as determined by the word count function of the word-processing program used to prepare this filing, excluding the parts of the brief exempted by Delaware Local Rule 7.1.3.

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